K081194

7. 510(k) Summary

MAY 29 2008

Sponsor:	RSB Spine, LLC 3030 Superior Ave., Suite 703 Cleveland, OH 44114 Phone: 216.241.2804 Fax: 216.241.2820
Contact Person:	James M. Moran, D. Eng. Vice President of Engineering and Chief Technical Officer
Proposed Trade Name:	InterPlate™ IFD
Classification:	Class II
Classification Name:	Spinal Intervertebral Body Fusion Device
Regulation:	888.3080
Device Product Code:	MAX, ODP
Device Description:	The InterPlate™ IFD System consists of plates, bone screws and screw covers. Various plate sizes are available to accommodate individual patient anatomy and graft material size. Screw covers are individually matched to the plate size.
Intended Use:	The InterPlate™ IFD is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The InterPlate™ C, CGC and PEEK OPTIMA® Cervical Systems are intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The InterPlate™ L and LGC Systems are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.
Materials:	The InterPlate™ C, CGC, L and LGC components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136). The InterPlate™ PEEK OPTIMA® Cervical IFD components are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) and Ti-6Al-4V titanium alloy as described by ASTM F2026 and ASTM F136, respectively. Radiographic markers within the InterPlate™ PEEK Cervical IFD are manufactured from Ti-6Al-4V titanium alloy (ASTM F136).
Substantial Equivalence:	Documentation was provided which demonstrated the InterPlate™ to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

RSB Spine, LLC
% Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, Ohio 44026-2141

Re: K081194
Trade Name: InterPlate™ Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: ODP, MAX
Dated: April 28, 2008
Received: April 28, 2008

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number: K081194

Device Name: **InterPlate™ Interbody Fusion Device**

Indications for Use:

The InterPlate™ Interbody Fusion Device (IFD) is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The InterPlate™ C, CGC and PEEK OPTIMA® Cervical Systems are intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment.

The InterPlate™ L and LGC Systems are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mpk

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081194